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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: CFN 1170454

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4012

February 6, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Shahid Aziz, M.D.
Vice President, Medical Affairs
Harbor Hospital Center
3001 S. Hanover Street
Baltimore, Maryland 21230

Dear Dr. Aziz:

During an inspection of your blood bank facility conducted by the Food and Drug Administration (FDA) from January 14 - 17, 1997, our investigator documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations, Parts 211 and 600-680. The following deviations were found:

1. Failure to establish and/or maintain adequate disposition records for autologous and therapeutic donations (21 CFR 606.160(b)(3)(i) and 606.160 (b)(1)(IV)).

2. Failure to maintain adequate records for therapeutic bleedings (21 CFR 606.160(b)(1)(IV)), in that the bleeds were not authorized by a physician and did not identify the donor's disease.

3. Failure to follow blood bank standard operating procedures (SOPs) (21 CFR 606.100(b)), such as the "Blood Bank Preventive Maintenance and QC Program," "Release of Blood in an Emergency Situation," inspection of refrigerators and ice machines, and the "temporary procedure" to be used when the plasma thawing bath is out of order.

4. Failure to ensure adequate supervisory review of quality control records (21 CFR 211.192).

The aforementioned violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

The deficiencies noted were listed on a form FDA-483, Inspectional Observations, and presented to and discussed with Thomas S. Gipson, M.D., Medical Director, at the close of the inspection. A copy of the FDA-483 is enclosed for your review.

You should take prompt measures to correct these deviations. Failure to do so may result in regulatory action without further notice. Such actions include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Wiley T. Williamson, III, Compliance Officer, Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201.

Sincerely,

George R. Brubaker, Ph.D.
Acting Director, Baltimore District

Enclosure